federal register

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-42037; T3H-FRL 2437-4]

Alkyltin Compounds; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice is EPA's response to the Interagency Testing Committee's designation that EPA consider chemical fate and environmental effects testing of seven alkyltin substances under section 4(a) of the Toxic Substances Control Act (TSCA). EPA is not initiating rulemaking under section 4(a) to require such testing at this time. At present, EPA does not believe that there is a sufficient basis to find that these substances may present an unreasonable risk to the environment, or that there is or may be substantial environmental release of these substances.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Officer (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-545, 401 M St., SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) or The Act (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations which require manufacturers and processors to test chemical substances and mixtures. Data developed through these test programs are used by EPA in assessing the risks that the tested chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC may designate up to 50 of its recommendations at any one time for priority consideration by EPA. EPA is required to respond within 12 months of the date of designation, either by initiating rulemaking under section 4(a) or by publication in the **Federal Register** reasons for not doing so.

On November 3, 1982, the ITC designated the seven alkyltin substances listed below for priority consideration in its Eleventh Report, published in the **Federal Register** of December 3, 1982, (47 FR 54624). The Committee recommended that these substances (see Table 1) be considered for testing for: (1) Chemical fate, including mobility of the substances from manufacturing and disposal sites, hydrolysis, biodegradation, and identification of persistent degradation products; and (2) acute and chronic toxicity to fish and aquatic invertebrates, toxicity to acquatic plants, and bioconcentration.

TABLE 1. ALKYLTIN SUBSTANCES

Chemical substances	CAS No.
Alkyltin Compounds;	
Dibutyltin @dilaurate	77-58-7
Dimethyltin S,S'-bis (isooctyl mercaptoacetate)	26636-01-1
Dibutyltin S,S'-bis (isooctyl mercaptoacetate)	25168-24-5
Dibutyltin bis (isooctyl maleate)	25168-21-2
Dibutyltin bis (lauryl mercaptide	1185-81-5
Monobutyltin tris (isoctyl mercaptoacetate)	25852-70-4
Monomethyltin tris (isooctyl mercaptoacetate)	54849-38-6

The ITC's recommendations of the designated substances were based on: (1) Substantial production; (2) their use as stabilizers in polyvinyl chloride (PVC) and chlorinated polyvinyl chloride (CPVC) products, especially piping for potable water; (3) the potential for exposure to the environment through leaching in their use as stabilizers in plastic materials and as catalysts, and through manufacturing wastes; and (4) the potential of these compounds for persistence and bioaccumulation in the environment, resulting in potential risk to environmental organisms. The ITC based its concerns for the potential environmental hazard posed by these seven alkyltin substances on their presumed structural similarity to certain trialkyltin substances which are registered under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) for use as pesticides and antifoulants. Presently there are no known TSCA uses for the trialkyltin substances even though some of them are listed on the TSCA inventory (Ref. 27).

In evaluating the ITC's testing recommendations for the seven designated alkyltin substances, EPA considered all relevant information, including the following: (1) Information presented in the ITC's Eleventh Report; (2) production volume, use, and exposure information reported by manufacturers of the alkyltins; and (3) other published and unpublished data available to the Agency, including any data submitted under TSCA section 8(d). The Agency also expects to use reported information from a recently proposed TSCA section 8(a) rule to verify the conclusions that it has made in this notice. EPA also considered the availability of validated analytical methods to identify and quantitate the alkyltins. Based on its evaluation, as discussed below, EPA is not initiating rulemaking at this time under section 4(a) to require environmental effects testing of the seven alkyltins.

II. Assessment of Exposure and Environmental Effects

A. Production, Release, Exposure

The seven ITC-designated alkyltin substances are methyl or butyltin compounds in which one or two alkyl groups are relatively strongly bound to tetravalent tin; the remaining tin bonds are more weakly bound to mercaptide, mercaptoacetate or ester anions. Few physical data are available on these substances. It is generally believed, however, that most of them are high boiling-point (low vapor pressure) liquids that have low solubility in water but may dissociate in water to form aquated compounds of moderate water solubility (Ref. 7). Only the methyltins have appreciable volatility (Ref. 21).

The ITC reported 1982 production ranges for each of the designated alkyltins between 0.5 and 4.6 million pounds per year (Ref. 35). Most of these compounds are produced and used as stabilizers for PVC, CPVC, or other plastics where they are present in concentrations ranging from 0.3 percent to 2.5 percent (Ref. 21). The plastics stabilized with these compounds are used mainly in construction applications such as pipe (including potable water pipe), conduits, floor and wall coverings, and outside siding (Ref. 21). Dibutyltin dilaurate is an exception because only 14 percent is used as a stabilizer, the bulk of it being used as a catalyst for polyurethane foams, as a chemical intermediate, or as an anthelmintic (anti-tapeworm agent) and coccidiostat for poultry (Refs. 7, 21). The latter two uses are not subject to TSCA jurisdiction. The use of dibutyltin dilaurate has declined sharply in recent years apparently due to the use of competitive agents which would account for a real decline in production and in the fraction used for catalysts (Ref. 21). Production of the six other category members is projected to increase at an average growth rate of six percent annually through 1986 (Ref. 34).

In assessing the potential environmental release and exposure to the designated alkyltins, EPA considered three main paths of potential release: leaching from plastics, release incidental to catalyst use, and release from both alkyltin manufacturing plants and PVC/CPVC fabrication plants. The Agency also considered other sources of these types of compounds in the environment, i.e., the potential release of butyltins from the chemical and biological degradation of tributyltin pesticides and the formation of methyltins from the biomethylation of inorganic tin present in the environment.

EPA's analysis of this information is presented below.

1. *Leaching from plastics.* Approximately 12 million pounds per year of the designated alkyltins are used as stabilizers in PVC and CPVC products. Most of these uses result in the alkyltins being dispersed into the environment encapsulated in a plastic matrix (Ref. 7). Although the ITC expressed concern about the leaching of the alkyltins from plastic products, especially from pipe used for potable water, EPA has found that any anticipated release would occur very slowly. The available evidence also indicates that what is released from the PVC/CPVC matrix are reaction products formed during the polymer stabilization process rather than intact alkyltins. Recent studies indicate that organotin compounds react with the polymer during stabilization to prevent the release of hydrogen chloride and subsequent degradation of the long polymer chains (Ref. 3). Only the reaction products, in the form of alkyltin chlorides, are available for leaching (Ref. 3).

In studies designed to determine whether or not organic forms of tin existed in potable water samples after contact with organotic stabilized PVC/CPVC under various environmental conditions, Boettner et al. (1982) reported that the maximum leaching rates for organotin compounds, detected as either dimethyltin dichloride or dibutyltin dichloride, are on the order of 10^{-6} mg/m²/second. The sustained rate appears to be about 10^{-8}/m²/second. These studies found no evidence of the anionic part of the stabilizer in the extractant water. These results indicate that the migration of intact organotin compounds from the plastic matrix is minimal, if it occurs at all, and calculated values for lifetime leaching are on the order of thousands of years (Ref. 7).

Using data generated in the Boettner study, EPA derived worst-case estimates expected for maximum environmental concentrations of alkyltins. The estimated concentrations apply to surface waters and are based on the release of alkyltins from PVC pipe and tubing used in domestic water supply systems (Ref. 36). EPA estimated, in a typical example, that the concentrations of alkyltin would be 6.67 $\times 10^{-6}$ ppb for the average stream flow and 6.11 $\times$ $^{-6}$ ppb for the minimum stream flow for the Potomac River. These levels, in the parts per quadrillion range, are expected to have little, if any, impact on the environment.

2. *Release incidental to catalyst use.* Three of the designated alkyltins are also used as polymer catalysts. The alkyltin manufacturers indicated that the total catalyst use of the designated alkyltins was about 0.174 million pounds per year, or 1.2 percent of total consumption for these substances (Ref. 24). In this use, the catalyst is added to the polymer in low concentrations (1 percent) and subsequently incorporated in the cured polymer matrix (Ref. 36). Thus, the leaching rate for the catalysts should be similar to that of the stabilizers; but, because of the lower production volumes, EPA believes they will have even less impact on the overall environmental burden of alkyltins than that generated from stabilizer use.

3. *Release from manufacturing/fabrication plants.* Other possible sources of the designated alkyltins are PVC/CPVC fabrication plants and alkyltin manufacturing plants. In the former case, release during fabrication should be low because almost all the alkyltin entering the fabrication plant leaves incorporated in the plastic (Ref. 7). There may, however, be small amounts of spillage or residue in discarded drums or containers. There may also be some loss from maintenance and cleaning of machinery. For manufacturing plants, release may be as high as 0.01 percent of production or approximately 1,500 pounds per year of total organotin produced (Ref. 36). M & T Chemicals, one of the major organotin producers in the U.S., estimated that 10–20 pounds of total tin each day reaches factory effluents after treatment and sludge recovery from its manufacturing operations (Refs. 7, 24). Eighty percent of this is estimated to be "organotin", 60–70 percent of which is diorganotin, the rest being monoorganotin. No estimation of the amount of trialkyltin or other organotin compounds leaving the plant was given (Ref. 17). Dealkylation of the tin compounds in the treatment system is expected. The waste treatment sludges containing tin residues are recovered and reprocessed to recover tin which has a value estimated at 6–7 dollars/pound (Ref. 17). No attempt has been made, nor is the technology available, to identify which specific compounds are being released by this process. It is EPA's opinion that, in any case, the potential release of the designated alkyltins from manufacturing and PVC/CPVC fabrication is expected to be low and should be considerably less than the alkyltins released to the environment from pesticide use (antifouling paints, fungicides, etc.).

4. *Degradation of trialkyltin pesticides.* Chemical fate studies that have been done on alkyltin substances have been performed primarily on the trialkyltins. These studies present evidence that the alkyltins degrade at moderate to slow rates under environmental conditions. They also indicate that the degradation of the tributyltin pesticides and antifoulants may be the most important source of di- and monobutyltin in the environment. There are four environmental processes that have been identified that demonstrate degradation of the trialkyltin compounds either by loss of the anion or loss of an alkyl group (i.e. transforming a trialkyltin to a dialkyltin, a dialkyltin to a monoalkyltin, and a monoalkyltin to elemental tin). These are: (1) Hydrolytic destannylation, which appears to proceed fairly slowly with half-lives on the order of months (Ref. 32); (2) photolysis, which proceeds at moderate rates with half-lives of days to weeks (Ref. 32); (3) biodegradation, which also proceeds fairly slowly, with half-lives also on the order of months (Refs. 29, 31 and 32); and (4) hydrolysis, whereby, the anions rapidly dissociate from the alkyltin cations when the substances are dissolved in water or some other solvent with half-lives on the order of days (Refs. 22 and 25). Therefore, the half-lives for degradation of the trialkyltins to di- and monoalkyltins is on the order of days to months and can be contrasted with the hundreds of years it takes for the leaching of dibutyltin from plastics (Ref. 7).

5. *Natural formation of methyltins in the environment.* The biomethylation of tin in the environment has been an area of recent study. Biomethylation of tin has been shown to occur in a bacterium (*Pseudomonas sp.*) isolated from the Chesapeake Bay (Ref. 2). Other studies also point to biomethylation of tin derived from anthropogenic sources as a possible primary source of increased levels of methyltin compounds in the environment (Refs. 4, 6, and 14). The chemistry behind the biomethylation of tin is complex (Refs. 9, 11, 26, and 41). Ridely et al. (1977) proposed a biological cycle for tin whereby Sn (II), by single-electron oxidation, or Sn (IV), by single-electron reduction, forms a reactive Sn (III) radical that can then form monomethyltins and, in successive, reversible reactions, dimethyltins, trimethyltins and tetramethyltin. Monitoring data by Braman and Tompkins (1979) also support biomethylation of tins in the environment as a source of environmental methyltin compounds. However, although biomethylation of tin appears to take place in the environment, the rate of this process is

currently unknown. Brinckman (1981) points out that "detailed or quantitative relationships cannot be inferred from the presently sketchy data, but it is clear that the extent of biomethylation of so-called non-essential or toxic metals and metalloids is probably partly limited to current capabilities for their detection."

B. Monitoring and Analytical Methods

Tin and alkyltin substances have been monitored for and detected in the environment. Monitoring studies of the aquatic environment have reported the presence of tin measured as inorganic tin, methyltin, butyltin and total tin (i.e., all tin substances, organic and inorganic, combined); other specific alkyltins (e.g., ethyltins) have not been reported. Generally, total tin levels reported in these studies are in the very low to middle parts per trillion range (Refs. 4, 6, 13, 14, 20, and 28). Some areas had higher concentrations; in an extreme instance, samples taken near a marina at Lake St. Clair, Toronto, Canada, revealed a total tin concentration of 24.7 ppb and a total butyltin concentration (mono-, di- and tributyltins) of 18.7 ppb (Ref. 20). Seidel *et al.* (1980) noted that, overall, tin concentrations in recent terrestrial and marine deposits are higher than preindustrial age deposits by a factor of approximately ten. They hypothesize that this increase must be due to anthropogenic sources of tin release. In support of this hypothesis, Byrd and Andreae (1982) state that the annual production of all tin (i.e., both organic and inorganic uses) is about 528 million pounds and this production rate exceeds the rate of natural input of tin from erosion by a factor of more than ten. (It should be noted in this context of overall environmental tin fluxes that the vast bulk of tin production goes into inorganic tin uses (such as tin-plating steel) with only 8.7 percent of world tin production presently being used to manufacture organotin chemicals (Ref. 39).)

Currently, there is no way to positively identify the origin of the organotins found in the environment. Analytical methods for identifying trace levels of alkyltins have been developed, but they are not standardized. The problem of identifying the anions, which might then allow identification of the parent tin compounds, is even more difficult and has not been accomplished for environmental samples. Hence, there are no means currently available to distinguish, in the environment, the alkyltins used in pesticides from those resulting from manufacturing sources or from those occurring naturally (e.g., by biomethylation). However, suspected sources have been identified. Butyltin pollution has been associated with the use of tributyltins as an anti-fouling agent in ship paints (Refs. 20 and 28). Furthermore, as noted above, a suspected primary source of increased levels of methyltin is organic and inorganic tin compounds which are subsequently biomethylated to methyltin forms by bacteria (Refs 4, 6, and 14). These sources of environmental exposure are not directly related to, and can be contrasted with, the low releases expected from the seven ITC-recommended alkyltins.

C. Environmental Effects

The ITC recommended that the designated mono- and dialkyltin compounds be considered for acute and chronic aquatic toxicity testing to plants and animals and bioconcentration testing. These recommendations were based on the structural similarity of these compounds to the highly toxic trialkyltins, which are registered and used exclusively as pesticides, and on their high calculated Log P values.

Much of the toxicity data for the environmental effects of the organotins is on the trialkyltin compounds. Of the alkyl-substituted tins, maximum toxicity to all forms of life occurs with the trialkylated forms (Ref. 42). For instance, acute toxicity studies in mammals (mice and rats) suggested that the toxicity of the alkyltins increases substantially with an increased degree of alkyl substitution on the tin atom (Refs. 16 and 33). Thus, the tri-substituted tins are considerably more toxic than the dialkyltins and the dialkyltins are more toxic than the monoalkyltins. The anions associated with the organotin moiety seem to have little effect on the observed toxicity. Acute toxicity data on algae, fungi, insects and fish with mono-, di-, and trialkyltins confirm this patten of increasing toxicity with increasing numbers of alkyl substituents on the tin atom (Refs 1, 8, 12, 15, 18, 19, 30, and 40). These studies indicate that whereas the trialkyltins are generally toxic at 1 to 1,000 ppb exposure concentrations, the mono- and dialkyltins are not toxic until exposure concentrations reach 0.1 to 1,000 ppm. Thus, the mono- and dialkyltins are two to three orders of magnitude less toxic than the trialkyltins, a factor apparently not taken into account by the ITC when they made their recommendation.

There are statistically significant correlations between the logarithm of the octanol-water partition coefficient (Log P) and fish bioconcentration factors (BCFs) for chemicals with Log P values between one and five (Refs. 23 and 38). However, recent laboratory studies indicate that this correlation does not necessarily hold for chemicals with Log P values greater than five (Refs. 10 and 38). Calculated Log P values for the seven designated alkyltins are between 8.6 and 16.8 (Ref. 37). In experiments on two dialkyltins and one monoalkyltin, Maeda and Nishikawa (1980a and 1980b) and Kidooka (1982) reported measured BCFs of 0.3 to 16 in carp after eight weeks of exposure. One of these compounds, *n*-butyltin (2-hydroxyalkyl (C=14)-1-thio) sulfide, has a structure similar to that the alkyltins designated by the ITC and has a calculated Log P value of 8.5 (Ref. 37). The predicted BCF for this particular compound is 3.2 million, using the alogrithm of Veith et al. (1979), Log BCF=0.85 Log P—0.70. However, the measured BCF for this chemical substance was only 3—16 (Ref. 15). The estimates of Log P, which are for the intact molecule, also do not hold if the anions are unstable, which is expected (see Unit II. A.). If the mercaptoacetate, mercaptide, etc., groups are lost by hydrolysis, for example, then the Log P values for these compounds would fall below two and there would again be little predicted potential for bioaccumulation. Therefore, the Agency believes that standard estimation techniques of bioconcentration from Log P estimates are not appropriate for this class of substances.

III. Decision not to Initiate Rulemaking

EPA has concluded that there is not a sufficient basis to find that there is substantial environmental release of the seven designated mono-or dialkyltins recommended by the ITC. Neither has EPA found evidence that the current manufacture, distribution in commerce, processing, use, or disposal of these substances may present an unreasonable risk of injury to the environment.

From the analysis presented in Unit II.A., EPA has determined that the environmental exposure to the designated alkyltins is extremely low (low parts per quadrillion). Although higher levels of alkyltins have been detected in the environment (levels in the parts per trillion range), the Agency believes that the primary source of this material is from degradation of the tributyltin pesticides to their mono-and/or dibutyltin degradation products. This conclusion is based on the observed levels of the compounds occurring in areas frequented by marine vessels known to use antifouling paints containing tributyltin pesticide compounds and the lack of evidence of significant release of the ITC-designated substances from industrial manufacturing and use. EPA's belief that the presence of methyltin detected in the environment is from naturally occurring biomethylation processes is supported by the studies discussed in Unit II.A., in which methyltins were detected in areas not subjected to industrial contamination. In addition, EPA has no reason to believe that the release of the ITC-designated substances from plastics or industry contributes significantly to environmental levels of alkyltins.

The Agency believes that chemical fate data exist to reasonably predict that the designated alkyltins will degrade at moderate to slow rates, i.e., days to months. As indicated in Unit II.A., these rates of degradation are relatively fast compared to the thousands of years required for the anticipated leaching of the mono-and dialkyltins from plastic products. EPA does not believe that these alkyltins would play a significant role in the potential accumulation of alkytated in environmental species.

While the bioconcentration potential of the designated alkyltins is estimated to be high, as discussed in Unit II.C., only a small proportion of these intact tin molecules are expected to reach the environment. In contrast, the alkyltin species leached as alkyltin chlorides, have calculated bioaccumulation value of less than 100. In addition, should the intact alkyltins reach the environment, expected rapid hydrolysis would result in compounds with a much lower potential for bioconcentration. The Agency also has evidence that standard estimation techniques of bioconcentration from Log P calculations are not appropriate for these substances. Therefore, based on the available data, EPA has concluded that chemical fate and bioconcentration testing cannot be supported under section 4 of TSCA at this time.

EPA has also concluded that the existing data do not support a finding that the designated alkyltin compounds "may present an unreasonable risk" to the environment. As discussed in Unit II. C., toxicity studies done on a variety of tri- ,di-, and monoalkyltins on a wide variety of organisms demonstrate that mono-and dialkyltins are two to three orders of magnitude less toxic than the trialkyltins. As noted above, the tributyltin pesticides are produced and distributed in the environment deliberately for biogenic uses and have been and are being evaluated by the Agency's Office of Pesticide Programs for those uses. EPA has no reason to believe that the seven designated mono- and dialkyltins are present in significant levels in the environment or that there exists a potential risk to the environment from their presence. Accordingly, EPA finds no current basis to require testing.

The Agency recognizes, however, that should the use or production of these seven mono-and dialkyltins change, then there could arise a potential for unreasonable risk of injury to the environment. Therefore, the Agency will be examining these substances for the potential issuance of a significant new use rule or other follow-up action.

III. References

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IV. Public Record

The EPA has established a public record for this testing decision (docket number OPTS–42037) which includes:

(1) **Federal Register** notice designating the alkyltin compounds to the Priority List and all public comments received thereon.

(2) Communications consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Published and unpublished data.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection in the OPTS Reading Room from a.m. 8:00 to 4:00 p.m., Monday through Friday, except legal holidays, in Rm. E–107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: October 27, 1983

William D. Ruckelshaus,
Administrator

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